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Docket No.: 3749-0112PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Toshiharu Suzuki et al.

Application No.: 10/577,008

Confirmation No.: 7226

Filed: April 25, 2006

Art Unit: N/A

For: MARKER PEPTIDE FOR ALZHEIMER'S
DISEASE

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:


Subsequent to the filing of the above-identified application on April 25, 2006, attached hereto is an English translation of the International Preliminary Report on Patentability (Forms PCT/IB/338; PCT/IB/373 and PCT/ISDA/237) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated:

SEP 14 2006

Respectfully submitted,

By 
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Attachments

From the INTERNATIONAL BUREAU

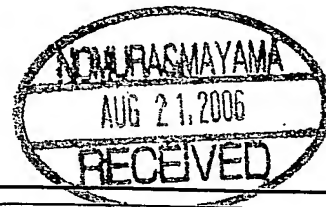
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NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

NOMURA, Kenichi
Nohki-kaikan Fourth Floor
3-chome
Kanagawa-ku, Yokohama-shi
Kanagawa 2210835
JAPON

30-1, Tsuruyacho



Date of mailing (day/month/year) 03 August 2006 (03.08.2006)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference FP-044PCT	
International application No. PCT/JP2004/016209	International filing date (day/month/year) 01 November 2004 (01.11.2004)
Applicant SUZUKI, Toshiharu et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP-044PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/016209	International filing date (<i>day/month/year</i>) 01 November 2004 (01.11.2004)	Priority date (<i>day/month/year</i>) 05 November 2003 (05.11.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant SUZUKI, Toshiharu			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 27 July 2006 (27.07.2006)
	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

FP-044PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/016209

International filing date (day/month/year)

01.11.2004

Priority date (day/month/year)

05.11.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

SUZUKI, Toshiharu

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016209

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☒

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016209

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 10-12

because:

☒ the said international application, or the said claims Nos. 10-12
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions described in Claims 10-12 relate to a method for diagnosis of the human body, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 10-12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/016209

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	4-9, 13, 15	YES
	Claims	1-3, 14	NO
Inventive step (IS)	Claims	4-9, 13, 15	YES
	Claims	1-3, 14	NO
Industrial applicability (IA)	Claims	1-9, 13-15	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: WO 02/22819 A1 (Universitat Zurich), 21 March 2002</p> <p>Document 2: JP 2003-164298 A (Takeda Chemical Industries, Ltd.), 10 June 2003</p> <p>On pages 75-77, document 1 describes a partial peptide corresponding to the extracellular domain of human calsyntenin-1 which is a peptide consisting of 89 amino acid residues.</p> <p>In terms of their full sequences the alcadein of the invention of this application and the calsyntenin-1 of document 1 are effectively identical proteins, and moreover the peptide described in document 1 matches the sequence of amino acids 764 through 852 in the amino acid sequence of SEQ ID NO:1 in this application. That is, the partial peptide described in document 1 is a part of the extracellular domain cut off from the N-terminal side of alcadein alpha, and considering that judging from page 8 of the specifications of this application, the C-terminal side corresponds to a part cleaved near the 852nd amino acid in SEQ ID NO:1 of this application, the partial peptide described in document 1 is identical to the inventions of Claims 1-3 of this application.</p> <p>On pages 61-65, document 1 describes preparing an R71 antibody using as the antigen a peptide consisting of the outer 87 amino acid residues of the extracellular domain adjoining the transmembrane domain of chicken calsyntenin-1, and describes that this R71 antibody also exhibits an immune reaction with respect to human calsyntenin-1. For the reasons given above, this antigen peptide is also the same as the inventions of Claims 1-3 of this application. Considering that the antigen proteins are the same, the R71 antibody thereto would exhibit an immunochemical reaction to the partial peptide of the invention of this application, and therefor the invention of Claim 14 of this application does not possess novelty because it is the same as the R71 described in document 1.</p> <p style="text-align: right;">Continued in Supplemental Box</p>			

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Document 1 describes that calsyntenin-1 is a calcium binding protein which serves as a protease substrate, and describes performing tests to specify its severed site. Document 2 describes that the XB31 α or β protein forms complexes with X11L and APP, and that such complex formation suppresses A β production. In terms of their amino acid sequences, calsyntenin-1 (document 1) and XB31 α are effectively identical proteins (with XB31 α lacking only 10 amino acid residues near the N terminal). However, neither document describes specifying the exact severed site of its extracellular domain or describes that it is cut off by the same enzyme as beta-amyloid and secreted outside the cell, nor would it be easy for a person skilled in the art to conceive that this secreted protein could be used as a marker for Alzheimer's disease.

Consequently, the inventions of Claims 4-9, 13 and 15 of this application appear to possess novelty and industrial applicability and to involve an inventive step.